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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/059,421	01/31/2002	Tetsuo Shibuya	YOR920010126US2	6845
21254 7590 05/15/2007 MCGINN INTELLECTUAL PROPERTY LAW GROUP, PLLC 8321 OLD COURTHOUSE ROAD SUITE 200 VIENNA, VA 22182-3817			EXAMINER LY, CHEYNE D	
			ART UNIT 2168	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/059,421

Applicant(s)

SHIBUYA ET AL.

Examiner

Cheyne D. Ly

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 March 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicants' arguments filed March 06, 2007 have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

2. Claims 1-30 are examined on the merits.

RESPONSE TO ARGUMENTS

3. On pages 11-15, Applicant argues that "Rigoutsos '99 does not teach or suggest a processor which *"determines whether said open reading frame includes at least part of a putative gene based on said occurrences of said patterns of amino acids located in said amino acid translation of said ORF."* Applicant's argument is not persuasive as discussed below.

4. The instant specification does not explicitly define the limitation of "putative gene." Therefore, the limitation of "putative gene" has been interpreted as exemplified by Applicant in the instant application. For example, Applicant provides an exemplary disclosure as to how the "ORF may be reported as a putative gene" (page 17, lines 7-11):

The inventive method 200 may, thus, identify (240) matches of patterns from the pattern database in the amino acid translation, for example, by locating instances (e.g., matches) of patterns from the pattern database in the candidate gene and determining if support goes above the given threshold value. If yes, the ORF may be reported as a putative gene, and if not, the inventive method 100 proceeds with the next ORF.

5. Further, the claims as amended recites "open reading frame includes at least part of a putative gene" wherein said limitation has been interpreted, as supported above, that any matching of at least two amino acids would identify a "putative gene" as claimed. A reasonable

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interpretation of the claimed invention is that the identifying of matching patterns from the pattern database in the amino acid translation such as the ORF “determin[es]...a putative gene”. Therefore, Ganguly in view of Rigoutsos renders the claimed invention obvious as discussed below.

6. Specific to page 11, lines 7-18, Applicant’s argument is not persuasive because the claims do not recite limitations that are being argued as being absent from the cited prior art. For example, Applicant argues that the claimed invention “including the best characteristics of statistical approaches and database similarity searches.” The claimed invention does not recite the argued limitation; therefore, citation of said limitation in the prior art is not required.

7. On page 11, beginning on line 19, to page 12, line 16, Applicant argued that Riogoutsos ’99 does not describe the limitation of “*determines whether said open reading frame includes at least part of a putative gene based on said occurrences of said **patterns of amino acids located in said amino acid translation of said ORF.***” Applicant’s argument is not persuasive because Ganguly has been cited to describe the limitation of Translates an open reading frame (ORF) of said DNA sequence into an amino acid (page 203, section 4.2, especially, “Locate open reading frames”, and page 206 in its entirety). Rigoutsos ’99 has been cited to describe the limitation of Locates in said amino acid translation occurrences of said patterns from said pattern database (page 228, column 2, lines 4-11, especially, “in the following ten ORFs...”); and Determines whether said open reading frame includes at least a part of a putative gene is said DNA sequence based on said occurrences of said patterns of amino acids located in said amino acid translation of said ORF (page 228, column 2, lines 4-11, especially, “Fe-S oxidoreductases”). The matching of patterns in the cited portion of Rigoutsos with the ORF of Ganguly is consistent with the

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matching to “determining...a putative gene” as exemplified by Applicant. Therefore, Ganguly in view of Rigoutsos renders the claimed invention obvious as discussed below.

8. On page 12, line 18, to page 15, Applicant argues that the pointed to passage of Rigoutsos “simply states that the amino acid sequences...**were known at the time to be**

oxidoreductases...Nowhere does Rigoutsos’99 describe how, where or why these two amino acids were so annotated...” Applicant’s argument is not persuasive because Applicant exemplifies the claimed method of determining putative genes by “correctly finding those of the ORFs that already have been reported in the public databases as putative genes...” (page 21, lines 2-5). The matching of patterns in the cited portion of Rigoutsos with the ORF of Ganguly is consistent with the matching to “determining...a putative gene” as exemplified by Applicant. Therefore, Ganguly in view of Rigoutsos renders the claimed invention obvious as discussed below.

9. On page 15, Applicant argues that “these references would not have been combined as suggested by the Examiner...these references are unrelated...” is not persuasive. Delcher describes an improvement to make GLIMMER more accurate for gene identification (Abstract etc., page 4639, column 2, last two lines). Therefore, one of ordinary skill in the art at the time of the instant invention would have been motivated by Delcher to improve the accuracy of GLIMMER by using the system described by Rigoutsos for specificity and sensitivity (Rigoutsos, page 224, column 2, last paragraph) for greater accuracy. Further, Ganguly describes a “database system...will greatly enhance current sequence analysis efforts, by providing a framework for integrating currently existing algorithms” (page 200, lines 9-12). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the instant

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invention to use the system as described by Ganguly, Rigoutsos and Delcher to improve accuracy in sequence analysis efforts.

10. Applicant's argument (pages 15-16) directed to the limitation of "determines whether said open reading frame includes at least part of a putative gene based on said occurrences of said **patterns of amino acids located in said amino acid translation of said ORF**" is not persuasive because Ganguly in view Rigoutsos describes the argued limitation as discussed above. Further, Delcher has been cited to describe the "ORF comprises a portion of said DNA sequence between a start codon and a stop codon" (page 4640 column 2, Table 5) as applied to claims 9, 26, and 30. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to use the system as described by Ganguly, Rigoutsos and Delcher to improve accuracy.

Claim Rejections - 35 USC § 112

11. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

12. Claims 1-30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **NEW MATTER.**

13. The instant rejection has been necessitated by claim amendments.

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14. Claim 1, line 9, recites “determines whether said open reading frame includes at least part of a putative gene” wherein said limitation has not been found in the specification, as originally filed. It is noted that Applicant provides an exemplary disclosure as to how the “ORF may be reported as a putative gene” (page 17, lines 7-11):

The inventive method 200 may, thus, identify (240) matches of patterns from the pattern database in the amino acid translation, for example, by locating instances (e.g., matches) of patterns from the pattern database in the candidate gene and determining if support goes above the given threshold value. If yes, the ORF may be reported as a putative gene, and if not, the inventive method 100 proceeds with the next ORF.

15. However, the specification does not provide written basis for the claimed invention which “determines...includes **at least part of a putative gene**” because one of ordinary skill would recognize that the claimed invention, as amended, is distinct from the invention described in the specification, as originally filed. The same issue is present in claims 16, 23, 29, and 30.

Claim Rejections - 35 USC § 103

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

17. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

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invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

18. **Claims 1-8, 10, 11, 13-23, 25, and 27-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ganguly et al. (1996) (Ganguly hereafter) in view of Rigoutsos et al. (1999) (Rigoutsos hereafter).**

19. This rejection is maintained with respect to claims **1-8, 10, 11, 13-23, 25, and 27-29**, as recited in the previous office action mailed December 06, 2006.

20. It is noted that Rigoutsos et al. (1998) has been cited to describe the well-known in the art characteristics of the Teiresias algorithm.

21. In regard to claim 1, Ganguly describes:

- a. An input device for inputting a genomic DNA sequence (page 200, section 2, The Data Model, and Figure 1);
- b. Translates an open reading frame (ORF) of said DNA sequence into an amino acid (page 203, section 4.2, especially, "Locate open reading frames", and page 206 in its entirety).

22. However, Ganguly does not describe the pattern database comprising patterns of amino acids and "locates...a putative gene in said DNA sequence."

23. Rigoutsos describes:

- c. A pattern database comprising patterns of amino acids (page 225, column 2, The Database section);
- d. A processor which:

- i. Locates in said amino acid translation occurrences of said patterns from said pattern database (page 228, column 2, lines 4-11, especially, “in the following ten ORFs...”); and
- ii. Determines whether said open reading frame includes at least a part of a putative gene is said DNA sequence based on said occurrences of said patterns of amino acids located in said amino acid translation of said ORF (page 228, column 2, lines 4-11, especially, “Fe-S oxidoreductases”).

24. Ganguly describes a “database system...will greatly enhance current sequence analysis efforts, by providing a framework for integrating currently existing algorithms” (page 200, lines 9-12). Rigoutsos describes a sequence analysis method using a database containing unaligned ORFs for pattern discovery (Abstract etc.). Therefore, one of ordinary skill in the art at the time of the invention would have been motivated by Ganguly to integrate said database system with the pattern database of Rigoutsos to greatly enhance current sequence analysis efforts.

Therefore, it would have been obvious to one of ordinary skill in the art to integrate the database system of Ganguly with the pattern database of Rigoutsos to greatly enhance current sequence analysis efforts.

25. In regard to claim 2, Rigoutsos and Ganguly describe the claim invention as cited above. Further, the court held that mere duplication of parts has no patentable significance unless a new and unexpected result is produced. See *In re Harza*, 274 F.2d 669, 124 USPQ 378 (CCPA 1960). Therefore, it would have been obvious to one of ordinary skill in the art to integrate the database system of Ganguly with the pattern database of Rigoutsos to greatly enhance current sequence analysis efforts.

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26. In regard to claim 3, Rigoutsos describes patterns comprise biologically significant patterns of amino acid sequences (page 225, column The Database section). Therefore, it would have been obvious to one of ordinary skill in the art to integrate the database system of Ganguly with the pattern database of Rigoutsos to greatly enhance current sequence analysis efforts.

27. In regard to claim 4, Rigoutsos describes processor identifies a match of a pattern from said pattern database in said amino acid translation (page 226, column 2, lines 4-14, page 228, column 2, lines 4-15, and Figure 8). Therefore, it would have been obvious to one of ordinary skill in the art to integrate the database system of Ganguly with the pattern database of Rigoutsos to greatly enhance current sequence analysis efforts.

28. In regard to claim 5, Rigoutsos describes patterns are derived from a parent database comprising at least one amino acid sequence (page 224, column 1, lines 36-39). Therefore, it would have been obvious to one of ordinary skill in the art to integrate the database system of Ganguly with the pattern database of Rigoutsos to greatly enhance current sequence analysis efforts.

29. In regard to claim 6, Rigoutsos describes patterns are derived from a parent database comprising at least one amino acid sequence fragment (page 224, column 1, lines 36-39, and page 225, column 2, The Database section). Therefore, it would have been obvious to one of ordinary skill in the art to integrate the database system of Ganguly with the pattern database of Rigoutsos to greatly enhance current sequence analysis efforts.

30. In regard to claim 7, Rigoutsos describes patterns are derived by using a pattern discovery algorithm (page 225, column 2, The Database section). Therefore, it would have been

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obvious to one of ordinary skill in the art to integrate the database system of Ganguly with the pattern database of Rigoutsos to greatly enhance current sequence analysis efforts.

31. In regard to claim 8, Rigoutsos describes patterns are derived by using the Teiresias algorithm (page 225, column 2, The Database section). Therefore, it would have been obvious to one of ordinary skill in the art to integrate the database system of Ganguly with the pattern database of Rigoutsos to greatly enhance current sequence analysis efforts.

32. In regard to claim 10, Rigoutsos describes processor reports said ORF as at least part of a putative gene when a predetermined number of pattern matches is identified in said amino acid translation (page 225, columns 1-2, 1D Dictionary / Selecting The Various Parameters section, and page 228, column 2, lines 4-16). Therefore, it would have been obvious to one of ordinary skill in the art to integrate the database system of Ganguly with the pattern database of Rigoutsos to greatly enhance current sequence analysis efforts.

33. In regard to claim 11, Rigoutsos describes each pattern is assigned a weight depending upon a relevance of said pattern in determining whether said ORF comprises at least part of a putative gene (page 224, column 2, lines 23-31, and page 226, column 2, lines 4-14). Therefore, it would have been obvious to one of ordinary skill in the art to integrate the database system of Ganguly with the pattern database of Rigoutsos to greatly enhance current sequence analysis efforts.

34. In regard to claim 13, Rigoutsos describes match is identified using a predetermined pattern matching algorithm (page 226, column 2, lines 4-14, page 228, column 2, lines 4-15, and Figure 8). Therefore, it would have been obvious to one of ordinary skill in the art to integrate

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the database system of Ganguly with the pattern database of Rigoutsos to greatly enhance current sequence analysis efforts.

35. In regard to claim 14, Rigoutsos describes a memory device for storing and instructions to be executed by said processor (page 223, column 2, lines 10-22). It is noted that Rigoutsos et al. (1998) describes processing the input set with TEIRESIAS required only a few seconds on an IBM Power-PC workstation (page 60, lines 1-3). Therefore, it would have been obvious to one of ordinary skill in the art to integrate the database system of Ganguly with the pattern database of Rigoutsos to greatly enhance current sequence analysis efforts.

36. In regard to claim 15, Rigoutsos describes a display device for displaying an output from said processor (page 223, column 2, lines 10-22, and Figures 8 and 9). It is noted that Rigoutsos et al. (1998) describes processing the input set with TEIRESIAS required only a few seconds on an IBM Power-PC workstation (page 60, lines 1-3). Therefore, it would have been obvious to one of ordinary skill in the art to integrate the database system of Ganguly with the pattern database of Rigoutsos to greatly enhance current sequence analysis efforts.

37. In regard to claims 16-23, 25, and 27-29, the citation of Rigoutsos and Ganguly above describe a method for using the system comprising the Teiresias algorithm, which anticipates the claimed invention as required by claims 16-23, 25, and 27-29. Therefore, it would have been obvious to one of ordinary skill in the art to integrate the database system of Ganguly with the pattern database of Rigoutsos to greatly enhance current sequence analysis efforts.

38. **Claims 9, 26, and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ganguly et al. (1996) (Ganguly hereafter) and Rigoutsos et al. (1999) (Rigoutsos hereafter)**

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as applied to claims 1-8, 10, 11, 13-23, 25, and 27-29 above, and further in view of Delcher et al. (1999) (Delcher hereafter).

39. This rejection is maintained with respect to claims **9, 26, and 30**, as recited in the previous office action mailed December 06, 2006.

40. Ganguly and Rigoutsos describe the invention as required by claims 1-8, 10, 11, 13-23, 25, and 27-29.

41. Specific to the limitation of “a display device...” of claim 30, Rigoutsos describes the claimed display device in Figures 8 and 9.

42. However, Ganguly and Rigoutsos do not describe the limitation of “ORF comprises a portion of said DNA sequence between a start codon and a stop codon” as required by claims 9, 26, and 30.

43. Delcher describes an improvement to make GLIMMER more accurate for gene identification (Abstract etc., page 4639, column 2, last two lines). Therefore, one of ordinary skill in the art at the time of the instant invention would have been motivated by Delcher to improve the accuracy of GLIMMER by using the system described by Ganguly and Rigoutsos for specificity and sensitivity (Rigoutsos, page 224, column 2, last paragraph) for greater accuracy.

44. In regard to claims 9, 26, and 30, Delcher describes ORF comprises a portion of said DNA sequence between a start codon and a stop codon (page 4640 column 2, Table 5).

45. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to use the system as described by Ganguly, Rigoutsos and Delcher to improve accuracy.

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46. It is noted that lines 8-9 of claim 26 recites optional limitation of “a sum...exceed a predetermined threshold” which has not been cited in either Rigoutsos or Delcher. Due to said being optional, the citation of said optional limitation is not required for the instant prior art rejection, because Ganguly, Rigoutsos, and Delcher have been cited to describe the alternative limitation of “a predetermined number of matches is identified in said amino acid translation.”

CONCLUSION

47. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

48. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

49. Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of

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document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

50. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199. The USPTO's official fax number is 571-272-8300.

51. Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Dune Ly, whose telephone number is (571) 272-0716. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

52. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tim Vo, can be reached on (571) 272-3642.

C. Dune Ly
Patent Examiner
5/14/07

